Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of LHRH agonist on the improvement of urinary retention compared with the effect of finasteride and tamsulosin alone

Protocol summary

Study aim
Evaluation of the synergistic effect of LHRH agonist (Leuprorelin acetate 7.5mg) with finasteride and tamsulosin on urinary retention compared with the effect of finasteride and tamsulosin on urinary retention

Design
Clinical trial with control group with randomized double blind parallel groups

Settings and conduct
Imam Reza Hospital of Mashhad . Covered packages / medications will be given to the patients according to the randomized envelope. Random numbers generated by Excel software are listed as odd / even numbers (intervention / control) and placed in separate envelopes, respectively. After opening each envelope, the nurse will, as defined by the couple or individual code, inject as prescribed or simply deliver routine medication to the patient. Also, these patients have no contact with each other and have no knowledge of each other's treatment process.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) the patient has acute urinary retention 2) is over 50 years of age. 3) first episode of urinary retention 4) no other treatment or indication of surgery 5) patient urinary retention due to BPH Exclusion criteria: a) no informed consent of the patient 2) a history of any cardiovascular and renal and metabolic diseases and seizures 3) a patient with fever mean T over 38 ° C 4) a high PSA level (above 4) suspected of having prostate cancer To strengthen.

Intervention groups
Intervention group or treatment group including group receiving routine benign prostate enlargement treatment (alpha-blocker treatment + 5 alphardectase inhibitor + LHRH agonist) Control group Benign prostate enlargement treatment group (alpha-blocker + 5-alpha reductase inhibitor)

Main outcome variables
Release from catheterization one month after acute urinary retention

General information

Reason for update
The number of samples entered was incorrect

Acronym

IRCT registration information
IRCT registration number: **IRCT20170417033489N3**
Registration date: **2019-10-17, 1398/07/25**
Registration timing: **prospective**

Last update: **2020-02-25, 1398/12/06**
Update count: **1**

Registration date
2019-10-17, 1398/07/25

Registrant information

Name
Salman Soltani

Name of organization / entity
Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-22, 1398/07/30

Expected recruitment end date
2020-01-20, 1398/10/30

Actual recruitment start date
2019-11-02, 1398/08/11

Actual recruitment end date

2019-12-31, 1398/10/10

Trial completion date

2020-01-30, 1398/11/10

Scientific title

The effect of LHRH agonist on the improvement of urinary retention compared with the effect of finasteride and tamsulosin alone

Public title

The effect of LHRH agonist on urinary retention

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The first acute urinary retention No other treatment No indication of surgery Patient's urinary retention is caused by BPH Minimum age of 50 years

Exclusion criteria:

Informed patient dissatisfaction History of any heart, liver, kidney, metabolic and seizure diseases Patients with fever mean T more than 38 degrees Celsius High PSA levels (above 4) which strengthen suspicion of prostate cancer

Age

From **50 years** old

Gender

Male

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **78**

Actual sample size reached: **77**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using Excel software. Random numbers are inserted in odd and even codes into the envelope, after the patient arrives at the admission criteria, and, if the patient is satisfied, the envelope is opened and will be assigned to the intervention or control group according to the patient's code. Paired and odd codes represent intervention and control groups.The codes are placed separately in the envelope so that the nurse who opens each envelope will not be aware of the allocation of the next envelope (until the next envelope is opened).

Blinding (investigator's opinion)

Double blinded

Blinding description

Evaluators and analysts will be unaware of intervention and control groups (the evaluator will only assess the extent of catheter release in the short term).

Placebo

Not used

Assignment

Parallel

Other design features

Sample size in each group was maximum predicted to be 39 people, and with predictable Decrease in the number of subjects it was 35 in each group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Qureshi building ,University Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

99191-91778

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.512

Health conditions studied

1

Description of health condition studied

Acute urinary retention in patients with BPH

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

Primary outcomes

1

Description

The rate of catheter release in acute urinary retention induced by BPH

Timepoint

One month after drug injection

Method of measurement

No need for re-catheterization

2

Description

IPSS Score

Timepoint

Before and one month after drug injection

Method of measurement

IPSS Questionnaire

3

Description
The incidence of drug side effects
Timepoint
One month after drug injection
Method of measurement
Ask the patient

4

Description
The amount of post voiding residue(PVR)
Timepoint
One day after leaving the cathedral
Method of measurement
Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: All patients will receive routine BPH treatment including alpha-blocker tamsulosin 0.4 mg single daily oral and alpha reductase inhibitor finasteride 5 mg single daily oral.In addition, patients in the intervention group will be given a single dose of LHRH agonist loperurelin acetate 7.5 mg at baseline.
Category
Treatment - Drugs

2

Description
Control group: All patients will receive routine BPH treatment including alpha-blocker tamsulosin 0.4 mg single daily oral and alpha reductase inhibitor finasteride 5 mg single daily oral.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Salman Soltani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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presidentoffice@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
50
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Salman Soltani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available